Heritage Information Systems, Inc.

SmartPA

Clinical Edit Criteria Proposal

Drug/Drug Class: Ranexa® Clinical Edit
Date: June 13, 2007
Prepared for:
Prepared by: Missouri Medicaid

☒ **New Criteria** ☐ **Revision of Existing Criteria**

Executive Summary

Purpose: Ensure appropriate utilization and control of Ranexa® (ranolazine extended-release tablets).

Why was this Issue Selected: Ranexa is a branded drug product containing ranolazine indicated for the treatment chronic angina. Roughly 6.3 million Americans are estimated to experience angia. The prevalence of angina rises with an increase in age. This product represents the first new pharmaceutical approach to treat angina in more than 20 years in the United States. Ranexa may produce changes in the electrocardiogram (QT_C interval prolongation); therefore it should be reserved for patients who have not achieved adequate response with other antianginal drugs. Myocardial ischemia and symptoms of angina occur when there is a deficit of oxygen supply relative to oxygen demand. The focus of therapy has been to correct this imbalance by providing therapy which alters hemodynamic variables such as lowering of blood pressure, lowering of heart rate, and coronary vasodilation which improves myocardial oxygen supply. Ranexa improves diastolic relaxation to reduce myocardial workload and reduces resistance to coronary blood flow and thus reduces myocardial ischemia.

Program-specific information:

Drug	Cost/Month (WAC)
• *Ranexa 500mgTablets*	*$165.00*

Setting & Population: Patients 18 years of age and older

Type of Criteria: ☐ **Increased risk of ADE** ☐ **Non-Preferred Agent** ☒ **Appropriate Indications** ☐

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Data Sources:	☐ Only administrative databases	☒ Databases + Prescriber-supplied

Setting & Population

- Drug for review Ranexa® (ranolaine extended-release tablets)
- Age range: Patients 18 years of age and older
- Gender: Male and female

Approval Criteria

- Documented electrocardiogram (EKG) prior to therapy initiation
- Patient > 18 years of age
- Documented adequate therapeutic intervention with 1 or more calcium channel blocker**, and**
- Documented adequate therapeutic intervention with 1 or more beta blocker **and**
- Documented adequate therapeutic intervention with 1 or more nitrate **or**
- Documented compliance on current therapy

Denial Criteria

- Claims for patients under 18 years of age (require clinical consultant review)
- Lack of adequate initial therapeutic intervention with reference product(s)
- Concurrent use of products in contraindicated therapeutic classes
    - CYP3A inhibitors (potent or moderately potent)
        - ketoconazole, diltiazem, verapamil, macrolides, protease inhibitors
    - Drugs metabolized by CYP2D6
        - tricyclic antidepressants, thioridazine, ziprasidone
    - Drugs that prolong QT_c interval
        - quinidine, sotalol, erythromycin, Tikosyn

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References

1. Facts and Comparisons, pg. 572a – 572c. 2006.
2. USPDI, Micromedex, 2006.
3. Lippincott, Williams, Wilkins. PDR Electronic Library, Montvale NJ; 2006.
4. CV Therapeutics, “Ranexa Product Submission”, Palo Alto, CA, 94304; March 2006.

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